

Message Text

UNCLASSIFIED

PAGE 01 BONN 02315 112206Z

67

ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 EB-07 COME-00 CIAE-00

INR-07 NSAE-00 MED-03 /041 W
----- 113641

R 111621Z FEB 75

FM AMEMBASSY BONN

TO SECSTATE WASHDC 7889

INFO AMCONSUL MUNICH

UNCLAS BONN 02315

FOLLOWING IS REPEAT OF MSG FROM MUNICH R 100715Z FEB 75,
TO AMEMBASSY BONN. BEING REPEATED TO SECSTATE FOR ACTION,
AND MUNICH FOR INFO.

QUOTE

UNCLAS MUNICH 0256

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, GW

SUBJECT: RECALL OF MEDICAL DEVICES: BECKMAN INSTRUMENTS

REF: (A) STATE 025629; (B) BONN 01994; (C) BONN 00840

1) AS INSTRUCTED REFTELS COMMERCIAL OFFICER CONTACTED MANAGER
OF BECKMAN INSTRUMENTS GMBH, GUENTHER RATH, REGARDING INADQUATELY
LABELED VITAL SIGNS MONITORS (VSM). MR. TATH CONFIRMED THAT
HE HAD RECEIVED WARNING LETTER, TWO ADHESIVE LABELS AND PREPAID
RETURN POSTCARDS.

2) HE STATED, HOWEVER, THAT HE DID NOT INTEND TO FORWARD LABELS
AND POSTCARDS TO END-USERS OF VSMS. HE DECLINED TO TAKE THESE
ACTIONS BECAUSE HE BELIEVES THAT SENDING LABELS AND POSTCARDS
IN ENGLISH TO END-USERS WOULD SERVE NO PURPOSE SINCE THEY WOULD
NOT BE UNDERSTOOD BY MAJORITY OF PERSONS USING VSMS. MOREOVER, HE
STATED THAT U.L. FINDINGS LEGALLY IRRELEVANT AS FAR AS HIS FIRM'S
LIABILITY IS CONCERNED AND THAT HIS OBLIGATION IS TO COMPLY
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WITH RULES AND REGULATIONS OF GERMAN STANDARDS AGENCY, V.D.E.

3) RATH EMPHASIZED, HOWEVER, THAT HE WOULD (A) IMMEDIATELY TAKE STEPS TO DETERMINE WHETHER VSMS WERE ACTUALLY BEING USED WITH CARDIAC CATHETERS BY END-USERS AND (B) TAKE WHATEVER PRECAUTIONARY MEASURES HE DEEMS NECESSARY TO DEAL WITH PROBLEM REFERRED TO IN REFTEL(A).

4) COMMERCIAL OFFICER URGED RATH TO DISTRIBUTE LABELS AND POSTACARS TO COMPLEMENT WHATEVER OTHER STEPS HE FELT NECESSARY, INDICATING THAT NON-COMPLIANCE WITH FDA RULINGS COULD POSSIBLY HAVE AFFECT ON BECKMAN INSTRUMENTS GMBH'S STATUS AS CONSIGNEE PARENT FIRM'S PRODUCTS. RATH REAFFIRMED THAT HE MUST DECLINE TO DISTRIBUTE LABELS AND POSTCARS.

5) AS INSTRUCTED REFTEL (C) WE WILL SEND LETTER TO RATH CONFIRMING INFORMATION GIVEN HIM BY TELEPHONE, WITH COPY TO EMBASSY.
SPIVACK

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HILLENBRAND

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
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Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, LABELING, CONSUMER PROTECTION, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 11 FEB 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975BONN02315
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Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750050-0266
From: BONN
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750255/aaaabxbw.tel
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Margaret P. Grafeld
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05 JUL 2006

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Status: NATIVE
Subject: RECALL OF MEDICAL DEVICES: BECKMAN INSTRUMENTS
TAGS: ETRD, EIND, TBIO, GE, BECKMAN INSTRUMENTS, VITAL SIGNS MONITORS
To: STATE
Type: TE
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